Reply to Office Action of April 15, 2004

Remarks

Claims 54-58 and 71-75 are pending in this case. With this Reply, claim 54 is amended to more particularly point out and distinctly claim the invention.

Applicants note with appreciation the withdrawal of the previous rejection under 35 U.S.C. 112, first paragraph. The new rejections are addressed below.

Rejection under 35 U.S.C. 112, second paragraph

Claims 54-58 and 71-75 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite due to the inadvertent removal of the word "antibody" from claim 54. Applicants respectfully request withdrawal of this rejection because the word "antibody" has been readded to claim 54 as suggested by Examiner Ewoldt.

Rejection under 35 U.S.C. 112, first paragraph

Claims 54-58 and 71-75 stand rejected under 35 U.S.C. 112, first paragraph as not providing written description in the specification for the method claimed in claim 54, in particular for the limitation where the anti-ds DNA antibody binds to the same epitope as the R4A antibody. Applicants respectfully request reconsideration and withdrawal of this rejection based on the following discussion.

While the cited discussion at page 11, line 28, through page 12, line 1, and further to line 5, cites the R4A antibody as a specific embodiment of the invention, the specification contains numerous references to the use of the peptides for preventing binding of unspecified anti-dsDNA antibodies to glomeruli of renal tissue. See page 2, lines 15-17; page 3, lines 16-19; page 4, line 19-20; page 11, lines 23-24; and page 29, lines 26-29 (original claim 38). Additionally, the specification establishes that the applicants recognized that prevention of binding of anti-dsDNA antibodies is determined by the epitope specificity of the antibody, not by the fact that the antibody is the R4A antibody. See page 2, lines 15-17 ("The present invention also provides peptide sequences which define epitopes recognized by pathogenic murine anti-dsDNA

antibodies"); and page 17, line 11. Thus, a skilled artisan would understand that the applicants envisioned at the time of filing that peptides preventing glomeruli binding by antibodies recognizing the same epitope as the R4A antibody are within the scope of the invention disclosed in the specification.

To satisfy the written description requirement, the subject matter of the claim in question does not need to be literally described (MPEP 2163.2). Rather, when claims are added that were not in the original specification, the written description requirement is satisfied when the specification "reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 227 USPQ 177, 179 (Fed. Cir. 1985), cited in MPEP 2163.2. Additionally, the specification need not describe every aspect of the technology supporting the claim in order to satisfy the written description requirement. Additionally, "[t]here is generally an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement." (MPEP 2163, page 2100-170). Information well known in the art need not be described in detail in the specification. *Hybridtech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986).

In the present case, the skilled artisan, reading the specification at the time of filing, would recognize that the applicants envisioned preventing binding of antibodies that bind to the same epitope as the R4A antibody, since the specification specifically describes the use peptide sequences which define epitopes recognized anti-dsDNA antibodies, e.g., at page 2, lines 15-17; additionally the specification describes the R4A antibody as an anti-dsDNA antibody. It is thus clear that the applicants envisioned at the time of filing the use of the peptides for preventing binding of anti-dsDNA antibodies that bind to the same epitope as the R4A antibody.

Appl. No. 08/833,838 Amdt. dated July 15, 2004 Reply to Office Action of April 15, 2004

Conclusion

In light of the above discussion, applicants respectfully request withdrawal of the rejection under 35 U.S.C. 112, first paragraph, and passage of the claims to allowance. If there are any minor matters preventing this, applicants request that Examiner Ewoldt contact the undersigned attorney.

It is believed that no fee is due with this filing. However, if there are any unanticipated fees that are required to maintain pendency of this application, authorization is given to withdraw those fees from Deposit Account No. 01-1785.

Respectfully submitted

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